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Attorneys for Defendants,
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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA INC. Plaintiffs, v. ACTAVIS LABORATORIES FL, INC., and ACTAVIS PHARMA, INC., Defendants.	Civil Action No.: 3:14-cv-07263-MLC-TJB **DEFENDANTS' ANSWER, DEFENSES AND COUNTERCLAIMS** ***Electronically Filed***
ACTAVIS LABORATORIES, FL., INC.	

Counterclaimant,	)
	)
v.	)
	)
ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA INC.	)
	)
Counterclaim Defendants.	)
	)
_____	)

Actavis Laboratories FL, Inc. ("Actavis Florida"), and Actavis Pharma, Inc. ("Actavis Pharma") (collectively, "Defendants"), by their attorneys hereby Answer the Complaint of AstraZeneca AB, Aktiebolaget Hassle, AstraZeneca LP, and Zeneca Inc. (collectively, "Plaintiffs") as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 et seq., and in particular under 35 U.S.C. § 271(e). This action relates to Abbreviated New Drug Application ("ANDA") No. 206364 filed by or for the benefit of Actavis Florida and Actavis Pharma (collectively, "Defendants" or "Actavis") with the United States Food and Drug Administration ("FDA") for approval to market generic versions of Plaintiffs' NEXIUM 24HR® pharmaceutical products that are sold in the United States.

Answer: Defendants lack knowledge and information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore deny same.

THE PARTIES

2. Plaintiff AstraZeneca AB ("AZ AB") is a corporation operating and existing under the laws of the Sweden, with its principal place of business at S-151 85 Södertälje, Sweden.

Answer: Defendants lack knowledge and information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore deny same.

3. Plaintiff Aktiebolaget Hässle ("Hässle") is a corporation organized and existing under the laws of Sweden, having its principal place of business at Mölndal, Sweden.

Answer: Defendants lack knowledge and information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore deny same.

4. Plaintiff AstraZeneca LP ("AZ LP") is a limited partnership operating and existing under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803. AZ LP holds an approved New Drug Application from the FDA for an esomeprazole magnesium formulation that it sells under the name NEXIUM 24HR®.

Answer: Defendants lack knowledge and information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore deny same.

5. Plaintiff Zeneca Inc. ("Zeneca") is a Delaware corporation having its principal place of business at Wilmington, Delaware. Zeneca has exclusive rights in the United States to market and sell products covered by United States Patent Nos. 6,369,085 and 7,411,070.

Answer: Defendants lack knowledge and information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore deny same.

6. Upon information and belief, Actavis Florida is a corporation organized and existing under the laws of Florida, having its principal place of business at 4955 Orange Drive, Davie, Florida 33314. Upon information and belief, Actavis Florida is in the business of, inter alia, developing, manufacturing, and obtaining regulatory approval of generic copies of branded pharmaceutical products throughout the United States, including within this district.

Answer: **Defendants admit that Actavis Florida is a Florida corporation having a place of business at 4955 Orange Drive, Davie, Florida 33141, and admit that Actavis Florida is in the business of, among other things, developing, manufacturing, and obtaining regulatory approval of generic pharmaceutical products for the United States market. Defendants deny the remaining allegations in this paragraph.**

7. Upon information and belief, Actavis Florida is a wholly-owned subsidiary of Andrx Corporation (a Delaware corporation, having its principal place of business at 4955 Orange Drive, Davie, Florida 33314), which is a wholly-owned subsidiary of Actavis, Inc. (a Nevada corporation, having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054).

Answer: **Admitted.**

8. On information and belief, Actavis Pharma is a corporation organized and existing under the laws of Delaware, having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Upon information and belief, Actavis Pharma is in the business of, inter alia, selling and distributing generic copies of branded pharmaceutical products in New Jersey and throughout the United States, including some that are manufactured by Actavis Florida and/or for which Actavis Florida is the named applicant of the approved ANDAs.

Answer: **Defendants admit that Actavis Pharma is a Delaware corporation having a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054, and admit that Actavis Pharma is in the business of, among other things, distributing and/or selling generic pharmaceutical products in the United States market, including products made by Actavis Laboratories Fl., Inc. or for**

which Actavis Laboratories Fl., Inc. is the applicant of an approved ANDA. Defendants deny the remaining allegations in this paragraph.

9. On information and belief, Actavis Pharma is a wholly owned subsidiary of Actavis, Inc.

Answer: Admitted.

BACKGROUND

The NDA

10. AZ LP is the holder of New Drug Application ("NDA") No. 204655 for NEXIUM 24HR® Esomeprazole Magnesium Delayed-Release Capsules, 20 mg. NEXIUM 24HR® is an over the counter drug approved for the treatment of frequent heartburn (2 or more days a week). Esomeprazole magnesium trihydrate is the active ingredient in NEXIUM 24HR®.

Answer: Defendants lack knowledge and information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore deny same.

The Patents-in-Suit

11. United States Patent No. 6,369,085 ("the '085 patent"), entitled "Form of S-Omeprazole," was duly and legally issued by the United States Patent and Trademark Office ("the USPTO") on April 9, 2002 to AZ AB, upon assignment from the inventors Hanna Cotton, Anders Kronstrom, Anders Mattson, and Eva Möller. The '085 patent claims, *inter alia*, magnesium salts of esomeprazole trihydrate, pharmaceutical compositions comprising the claimed salts, methods of treatment using the claimed salts, and processes for preparing the claimed salts. A true and correct copy of the '085 patent is attached as Exhibit A.

Answer: Defendants admit that the '085 patent is entitled "Form of S-Omeprazole" and states on its face that it issued on April 9, 2002. Defendants admit that Exhibit A purports to be a copy of the '085 patent. Defendants lack knowledge and

information sufficient to form a belief about the truth of the remaining allegations in this paragraph, and therefore deny same.

12. Plaintiff AZ AB has been and still is the owner of the ’085 patent. The ’085 patent will expire on May 25, 2018, and pediatric exclusivity relating to the ’085 patent expires on November 25, 2018.

Answer: Defendants lack knowledge and information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore deny same.

13. United States Patent No. 7,411,070 (“the ’070 patent”), entitled “Form of S-omeprazole,” was duly and legally issued by the USPTO on August 12, 2008 to AZ AB upon assignment from inventors Hanna Cotton, Anders Kronstrom, Anders Mattson, and Eva Moller. The claims of the ’070 patent are directed to, *inter alia*, magnesium salts of esomeprazole trihydrate and processes for preparing the claimed salts. A true and correct copy of the ’070 patent is attached as Exhibit B.

Answer: Defendants admit that the '070 patent is entitled "Form of S-omeprazole" and states on its face that it issued on August 12, 2008. Defendants admit that Exhibit B purports to be a copy of the '070 patent. Defendants lack knowledge and information sufficient to form a belief about the truth of the remaining allegations in this paragraph, and therefore deny same.

14. Plaintiff AZ AB has been and still is the owner of the ’070 patent. The ’070 patent will expire on May 25, 2018, and pediatric exclusivity relating to the ’070 patent expires on November 25, 2018.

Answer: Defendants lack knowledge and information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore deny same.

The ANDA

15. On information and belief, Actavis Florida filed ANDA No. 206364 with the FDA under 21 U.S.C. § 355(j) to obtain FDA approval for the commercial manufacture, use, importation, offer for sale, and sale in the United States of esomeprazole magnesium delayed-release capsules, 20 mg ("Actavis's Esomeprazole Magnesium Delayed-Release Capsules"), which are generic versions of Plaintiffs' NEXIUM 24HR® Esomeprazole Magnesium Delayed-Release Capsules, in a 20 mg dosage form.

Answer: Admitted.

16. By letter dated October 7, 2014 (the "ANDA Notice Letter"), Actavis Florida notified Plaintiffs that Actavis Florida had filed ANDA No. 206364 seeking approval to market Actavis's Esomeprazole Magnesium Delayed-Release Capsules and that Actavis Florida was providing information to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95.

Answer: Defendants admit that Actavis Florida sent to Plaintiffs a letter dated October 7, 2014 ("the Notification Letter"). Defendants admit that the Notification Letter stated that Actavis Florida had filed ANDA No. 206364 seeking approval to market Actavis' Esomeprazole Magnesium Delayed-Release Capsules. Defendants otherwise deny the allegations in this paragraph.

17. On information and belief, Actavis Florida sells products manufactured by Actavis Pharma in New Jersey and throughout the United States.

Answer: Denied.

JURISDICTION AND VENUE

18. Subject matter jurisdiction over this action is proper pursuant to the provisions of Title 28, United States Code, Sections 1331 and 1338(a).

Answer: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest that the Court has subject matter jurisdiction with respect to allegations made pursuant to 35 U.S.C. 271(e)(2)(A). Defendants otherwise deny the allegations in this paragraph.

19. On information and belief, Defendant Actavis Pharma is a corporation organized and existing under the laws of Delaware, having its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

Answer: Soley for purposes of this action, Defendants do not contest personal jurisdiction. Defendants otherwise deny the allegations in this paragraph.

20. On information and belief, Actavis Florida, either directly or through one or more of its wholly owned subsidiaries and/or agents, develops, manufactures, distributes, markets, offers to sell, and sells generic drug products for sale and use throughout the United States, including within the judicial district.

Answer: Solely for purposes of this action, Defendants do not contest personal jurisdiction. Defendants otherwise deny the allegations in this paragraph.

21. On information and belief, Actavis Pharma, with the assistance and/or at the direction of Actavis Florida, develops, manufactures, distributes, markets, offers to sell, and sells generic drug products for sale and use throughout the United States, including within the judicial district.

Answer: Solely for purposes of this action, Defendants do not contest personal jurisdiction. Defendants otherwise deny the allegations in this paragraph.

22. On information and belief, Defendants are in the business of developing, formulating, manufacturing, marketing, offering to sell, selling, and commercializing pharmaceutical products.

Answer: Solely for purposes of this action, Defendants do not contest personal jurisdiction. Defendants otherwise deny the allegations in this paragraph.

23. On information an belief, Defendants acted in concert to develop Actavis's Esomeprazole Magnesium Delayed-Release Capsules and to seek approval from the FDA to sell Actavis's Esomeprazole Magnesium Delayed-Release Capsules throughout the United States, including within this judicial district.

Answer: Solely for purposes of this action, Defendants do not contest personal jurisdiction. Defendants otherwise deny the allegations in this paragraph.

24. On information and belief and as stated in the ANDA Notice Letter, Actavis Florida prepared and filed ANDA No. 206364.

Answer: Solely for purposes of this action, Defendants do not contest personal jurisdiction. Defendants otherwise deny the allegations in this paragraph.

25. On information and belief and as stated in the ANDA Notice Letter, the FDA received ANDA No. 206364 from Actavis Florida.

Answer: Solely for purposes of this action, Defendants do not contest personal jurisdiction. Defendants otherwise deny the allegations in this paragraph.

26. On information and belief by virtue of, inter alia, Actavis Florida's relationship with Actavis Pharma in connection with the preparation and/or filing of ANDA No. 206364 and the sales-related activities of Defendants in New Jersey, including but not limited to the

substantial, continuous, and systematic distribution, marketing, and/or sales of pharmaceutical products to residents of New Jersey, this Court has personal jurisdiction over Actavis Florida.

Answer: Solely for purposes of this action, Defendants do not contest personal jurisdiction. Defendants otherwise deny the allegations in this paragraph.

27. On information and belief, by virtue of, inter alia, Defendants' continuous and systematic contacts with New Jersey, including but not limited to the above-described contacts, and the actions on behalf of Defendants in connection with ANDA No. 206364, this Court has personal jurisdiction over Defendants. These activities satisfy due process and confer personal jurisdiction over Defendants consistent with New Jersey law.

Answer: Solely for purposes of this action, Defendants do not contest personal jurisdiction. Defendants otherwise deny the allegations in this paragraph.

28. Venue is proper in this District pursuant to the provisions of Title 28, United States Code, Sections 1391(c) and (d), and 1400 (b).

Answer: Solely for purposes of this action, Defendants do not contest the propriety of venue in the District.

COUNT 1: INFRINGEMENT OF THE '085 PATENT

29. Plaintiffs incorporate by reference paragraphs 1-28 of this Complaint as if fully set forth herein.

Answer: Defendants restate and incorporate each of their responses to paragraphs 1-28 as if fully set forth herein.

30. On information and belief, Defendants submitted ANDA No. 206364 to the FDA under 21 U.S.C. § 355(j) in order to obtain approval to market Actavis's Esomeprazole Magnesium Delayed-Release Capsules in the United States before the expiration of the '085 patent.

Answer: **Actavis Florida admits that it submitted ANDA No. 206364 to the FDA under 21 U.S.C. § 355(j) in order to obtain approval to market Esomeprazole Magnesium Delayed-Release Capsules in the United States before the expiration of the '085 patent. Defendants otherwise deny the allegations in this paragraph.**

31. By their ANDA Notice Letter, Defendants informed Plaintiffs that they had submitted to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the '085 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation into the United States of Actavis's Esomeprazole Magnesium Delayed-Release Capsules.

Answer: **In its Notification Letter, Actavis Florida informed Plaintiffs that it had submitted to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the '085 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation into the United States of Actavis's Esomeprazole Magnesium Delayed-Release Capsules. Defendants otherwise deny the allegations in this paragraph.**

32. Under 35 U.S.C. § 271(e)(2)(A), the submission by Defendants to the FDA of ANDA No. 206364 to obtain approval for the commercial manufacture, use, sale, offer for sale, or importation into the United States of Actavis's Esomeprazole Magnesium Delayed-Release Capsules before the expiration of the '085 patent constitutes infringement of one or more claims of the '085 patent, either literally or under the doctrine of equivalents.

Answer: **Denied.**

33. On information and belief, Actavis's Esomeprazole Magnesium Delayed-Release Capsules, if approved by the FDA, will be prescribed and administered to human patients in a

therapeutically effective amount to inhibit gastric acid secretion and for the treatment of gastrointestinal inflammatory disease. On information and belief, this administration will occur at Defendants' active behest and with their intent, knowledge, and encouragement. On information and belief, Defendants will actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '085 patent.

Answer: Denied.

34. The ANDA Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding all defenses, does not allege invalidity or unenforceability of any claims of the '085 patent. By not alleging invalidity or unenforceability, Defendants effectively admit that the '085 patent is both valid and enforceable.

Answer: Denied.

35. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

Answer: Denied.

COUNT 2: INFRINGEMENT OF THE '070 PATENT

36. Plaintiffs incorporate by reference paragraphs 1-28 of this Complaint as if fully set forth herein.

Answer: Defendants restate and incorporate each of their responses to paragraphs 1-28 as if fully set forth herein.

37. On information and belief, Defendants submitted ANDA No. 206364 to the FDA under 21 U.S.C. § 355(j) in order to obtain approval to market Actavis's Esomeprazole Magnesium Delayed-Release Capsules in the United States before the expiration of the '070 patent.

Answer: **Actavis Florida admits that it submitted ANDA No. 206364 to the FDA under 21 U.S.C. § 355(j) in order to obtain approval to market Esomeprazole Magnesium Delayed-Release Capsules in the United States before the expiration of the '070 patent. Defendants otherwise deny the allegations in this paragraph.**

38. By their ANDA Notice Letter, Defendants informed Plaintiffs that they had submitted to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the '070 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation into the United States of Actavis's Esomeprazole Magnesium Delayed-Release Capsules.

Answer: **In its Notification Letter, Actavis Florida informed Plaintiffs that it had submitted to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the '070 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation into the United States of Actavis's Esomeprazole Magnesium Delayed-Release Capsules. Defendants otherwise deny the allegations in this paragraph.**

39. Under 35 U.S.C. § 271(e)(2)(A), the submission by Defendants to the FDA of ANDA No. 206364 to obtain approval for the commercial manufacture, use, sale, offer for sale, or importation into the United States of Actavis's Esomeprazole Magnesium Delayed-Release Capsules before the expiration of the '070 patent constitutes infringement of one or more claims of the '070 patent, either literally or under the doctrine of equivalents.

Answer: **Denied.**

40. On information and belief, Actavis's Esomeprazole Magnesium Delayed-Release Capsules, if approved by the FDA, will be prescribed and administered to human patients in a

therapeutically effective amount to inhibit gastric acid secretion and for the treatment of gastrointestinal inflammatory disease. On information and belief, this administration will occur at Defendants' active behest and with their intent, knowledge, and encouragement. On information and belief, Defendants will actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '070 patent.

Answer: Denied.

41. The ANDA Notice Letter, which is required by statute and regulation to provide a full and detailed explanation regarding all defenses, does not allege invalidity or unenforceability of any claims of the '070 patent. By not alleging invalidity or unenforceability, Defendants effectively admit that the '070 patent is both valid and enforceable.

Answer: Denied.

42. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

Answer: Denied

PRAYER FOR RELIEF

Defendants deny that Plaintiffs are entitled to the relief requested in the Complaint.

DEFENSES

FIRST DEFENSE – NON-INFRINGEMENT OF U.S. PATENT NO. 6,369,085

Defendants do not and will not infringe, induce infringement of, and/or contribute to the infringement of, and/or contribute to the infringement of, any valid and enforceable claim of the '085 patent.

SECOND DEFENSE – INVALIDITY OF U.S. PATENT NO. 6,369,085

One or more claims of the '085 patent are invalid for failure to satisfy the provisions of one or more of Sections 101, 102, 103, and/or 112 of Title 35 of the United States Code.

THIRD DEFENSE – NON-INFRINGEMENT OF U.S .PATENT NO. 7,411,070

Defendants do not and will not infringe, induce infringement of, and/or contribute to infringement of, any valid and enforceable claim of the '070 patent.

FOURTH DEFENSE – INVALIDITY OF U.S. PATENT NO. 7,411,070

One or more claims of the '070 patent are invalid for failure to satisfy the provisions of one or more of Sections 101, 102, 103, and/or 112 of Title 35 of the United States Code.

FIFTH DEFENSE – FAILURE TO STATE A CLAIM

The Complaint is subject to dismissal for failure to state a claim upon which relief may be granted.

COUNTERCLAIMS

Defendant/Counterclaimant Actavis Laboratories, FL, Inc. ("Actavis Florida"), hereby asserts counterclaims against Plaintiffs/Counterdefendants AstraZeneca AB, Aktiebolaget Hässle, AstraZeneca LP, and Zeneca, Inc. as follows:

PARTIES

1. Actavis Florida is a corporation organized and existing under the laws of the State of Florida, having a place of business at 4955 Orange Drive, Davie, Florida 33314.

2. Plaintiff AstraZeneca AB (“AZ AB”) is a corporation operating and existing under the laws of the Sweden, with its principal place of business at S-151 85 Södertälje, Sweden.

3. Plaintiff Aktiebolaget Hässle (“Hässle”) is a corporation organized and existing under the laws of Sweden, having its principal place of business at Mölndal, Sweden.

4. Plaintiff AstraZeneca LP (“AZ LP”) is a limited partnership operating and existing under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803. AZ LP holds an approved New Drug Application from the FDA for an esomeprazole magnesium formulation that it sells under the name NEXIUM 24HR®.

5. These counterclaims seek a declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202.

6. This Court has subject matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1138(a), 2201, 2202 and 35 U.S.C. § 271(e)(2).

7. This Court has personal jurisdiction over Plaintiffs on the basis of, *inter alia*, its contacts with the District of New Jersey relating to the subject matter of this action, including having filed this suit.

8. Venue is proper 28 U.S.C. §§ 1391 and 1400(b) and by Plaintiffs' choice of forum.

BACKGROUND

9. This is an action based upon an actual controversy between the parties concerning the invalidity and noninfringement of United States Patent Nos. 6,369,085 ("the '085 patent") and 7,411,070 ("the '070 patent"); Actavis Florida's right to continue to seek approval of ANDA No. 206364 to engage in the commercial manufacture, use, and/or sale of Esomeprazole Magnesium Delayed-Release Capsules, 20 mg; and the right of Actavis Florida to sell, market, distribute or otherwise commercialize the product described in ANDA No. 206364.

10. Actavis Florida has submitted ANDA No. 206364 to the United States Food and Drug Administration ("FDA") for approval to engage in the commercial manufacture, importation, use or sale of generic Esomeprazole Magnesium Delayed-Release Capsules, 20 mg dosage.

11. The patents-in-suit are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") for the drug Nexium 24®.

12. On information and belief, and based on Plaintiffs' allegations, Plaintiffs are the holder of the New Drug Application No. 204655 for Nexium 24® containing the active ingredient esomeprazole magnesium trihydrate.

13. Plaintiffs caused the patents-in-suit to be listed in the Orange Book in association with Nexium 24®.

14. As a consequence of listing the patents-in-suit in the Orange Book, Plaintiffs were and are representing to the world that the patents-in-suit claim Nexium 24® and esomeprazole magnesium trihydrate, and that patent infringement actions relating to the patents-in-suit could reasonably be expected to be brought against unlicensed filers of ANDAs for which patent certification would be required.

15. Actavis Florida certified to the FDA in its ANDA No. 206364 that, in its opinion and to the best of its knowledge, its proposed esomeprazole magnesium product will not infringe any valid and/or enforceable claim of the patents-in-suit.

16. Actavis Florida notified Plaintiffs of the factual and legal bases for its certification with respect to the patents-in-suit in a letter dated October 7, 2014 ("Notification Letter").

17. The Notification Letter included an offer of confidential access pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

18. Plaintiffs have filed in this Court an infringement action against Actavis Florida to enforce the patents-in-suit.

19. In the Complaint, Plaintiffs allege that Actavis Florida has committed an act of infringement under 35 U.S.C. § 271(e) by filing ANDA No. 206364 seeking FDA approval to sell generic versions of Nexium 24® in the United States prior to the expiration of the patents-in-suit.

20. In the Complaint, Plaintiffs also allege that Actavis Florida will induce infringement of the patents-in-suit and/or contribute to the infringement of the patents-in-suit by others.

21. Actavis Florida has denied infringement of the patents-in-suit.

22. Actavis Florida has further asserted that the patents-in-suit are invalid for failure to satisfy the provisions of one or more of Sections 101, 102, 103, and/or 112 of Title 35 of the United States Code.

23. In view of the foregoing, a conflict of asserted rights has arisen between Actavis Florida and Plaintiffs with respect to the non-infringement and invalidity of the relevant claims of the patents-in-suit, with respect to Actavis Florida's right to obtain FDA approval to engage in the commercial manufacture, importation, use, offer for sale, or sale of the products described in ANDA 206364. An actual controversy therefore exists between Actavis Florida and Plaintiffs.

FIRST COUNTERCLAIM

Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,369,085

24. Actavis Florida repeats and realleges paragraphs 1-23 of its Counterclaims as if set forth specifically herein.

25. Actavis Florida does not infringe any valid, enforceable claim of the '085 patent, directly, indirectly, literally or under the doctrine of equivalents.

26. The sale, offer for sale, manufacture, importation or use of Actavis Florida's esomeprazole magnesium delayed-release capsules will not constitute infringement of any valid, enforceable claim of the '085 patent, either directly, indirectly, literally or under the doctrine of equivalents.

SECOND COUNTERCLAIM

Declaratory Judgment of Invalidity of U.S. Patent No. 6,369,085

27. Actavis Florida repeats and realleges paragraphs 1-23 of its Counterclaims as if set forth specifically herein.

28. One or more claims of the '085 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in 35 U.S.C. §§ 101, 102, 103 and/or 112.

THIRD COUNTERCLAIM

Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,411,070

29. Actavis Florida repeats and realleges paragraphs 1-23 of its Counterclaims as if set forth specifically herein.

30. Actavis Florida does not infringe any valid, enforceable claim of the '070 patent, directly, indirectly, literally or under the doctrine of equivalents.

31. The sale, offer for sale, manufacture, importation or use of Actavis Florida's esomeprazole magnesium delayed-release capsules will not constitute infringement of any valid, enforceable claim of the '070 patent, either directly, indirectly, literally or under the doctrine of equivalents.

FOURTH COUNTERCLAIM

Declaratory Judgment of Invalidity of U.S. Patent No. 7,411,070

32. Actavis Florida repeats and realleges paragraphs 1-23 of its Counterclaims as if set forth specifically herein.

33. One or more claims of the '070 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in 35 U.S.C. §§101, 102, 103 and/or 112.

FIFTH COUNTERCLAIM

Failure to State a Claim Under 35 U.S.C. § 271(a)

34. Actavis Florida repeats and realleges paragraphs 1-23 of its Counterclaims as if set forth specifically herein.

35. Plaintiffs' Complaint fails to state a claim for which relief can be granted under 35 U.S.C. § 271(a).

PRAYER FOR RELIEF

WHEREFORE, Actavis Florida prays for the following relief:

A. That all claims against Actavis Florida be dismissed with prejudice, that all relief requested by Plaintiffs be denied and that Plaintiffs take nothing by its Complaint;

B. That a judgment be entered declaring that Actavis Florida has not and does not infringe, directly, indirectly, literally or under the doctrine of equivalents any valid and enforceable claim of United States Patent Nos. 6,369,085 and 7,411,070; that Actavis Florida has a lawful right to obtain FDA approval of ANDA No. 206364; and further that Actavis Florida has a lawful right to manufacture, import, use, sell and/or offer to sell its esomeprazole magnesium product in the United States once approved by the FDA;

C. That a judgment be entered declaring that the claims of the United States Patent Nos. 6,369,085 and 7,411,070 are invalid for failure to comply with one or more of the conditions for patentability set forth in 35 U.S.C. §§101, 102, 103 and/or 112;

D. That Plaintiffs, its parents and/or subsidiaries and its agents, representatives, attorneys and those persons in active concert or participation with them who receive actual notice thereof be preliminarily and permanently enjoined from threatening or initiating infringement litigation against Defendants or any of their customers, dealers or suppliers or any prospective or present sellers, dealers, distributors or customers of Actavis Florida or charging any of them either orally or in writing with infringement of United States Patent Nos. 6,369,085 and 7,411,070;

E. That a judgment be entered declaring that this action is an exceptional case within the meaning of 35 U.S.C. § 285, and that Actavis Florida is entitled to recover its reasonable attorneys' fees upon prevailing in this action;

F. That Actavis Florida be awarded costs, attorneys' fees and other relief, both legal and equitable, to which they may be justly entitled; and

G. That Actavis Florida be awarded such other and further relief as is just and proper.

Dated: January 26, 2015

By: *s/ Liza M. Walsh*

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Attorneys for Defendants,
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Actavis Pharma, Inc.

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is not the subject of any other action pending in any court, or any pending arbitration or administrative proceeding, but it is related to the subject matter of the following actions:

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC. v. MYLAN LABORATORIES LTD. and MYLAN, INC.*, C.A. No. 3:12-cv-01378-JAP-TJB (District of New Jersey).

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC. v. WATSON LABORATORIES, INC. – FLORIDA*, C.A. No. 3:13-cv-01669-JAP-TJB (District of New Jersey).

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC. and KBI-E INC. v. WOCKHARDT LIMITED and WOCKHARDT USA LLC*, C.A. No. 3:13-cv-04854-JAP-TJB (District of New Jersey).

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC v. HANMI USA, INC., HANMI PHARMACEUTICAL CO., LTD., HANMI FINE CHEMICAL CO., LTD, and HANMI HOLDINGS CO., LTD.*, C.A. No. 3:11-cv-00760-JAP-TJB (District of New Jersey).

- *ASTRAZENECA AB; AKTIEBOLAGET HÄSSLE; ASTRAZENECA LP; KBI INC.; and KBI-E INC. v. AUROBINDO PHARMA LIMITED and AUROBINDO PHARMA USA Inc.*, C.A. No. 3:13-cv-7298-JAP-TJB (District of New Jersey).

- *ASTRAZENECA AB; AKTIEBOLAGET HÄSSLE; ASTRAZENECA LP; KBI INC.; and KBI-E INC. v. KREMERS URBAN PHARMACEUTICALS, KREMERS URBAN DEVELOPMENT CO., and KREMERS URBAN LLC*, C.A. No. 3:13-cv-7299-JAP-TJB (District of New Jersey).

The foregoing cases involve NEXIUM®, a product marketed by AstraZeneca that contains an esomeprazole magnesium formulation. The NEXIUM® cases have been assigned to Hon. Joel A. Pisano, U.S.D.J.

Dated: January 26, 2015

By: *s/ Liza M. Walsh*

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CERTIFICATION PURSUANT TO L. CIV. R. 201.1

Pursuant to Local Civil Rule 201.1, Actavis Laboratories FL, Inc. and Actavis Pharma, Inc., through its attorneys, certify that the above captioned matter is not subject to compulsory arbitration.

Dated: January 26, 2015

By: *s/ Liza M. Walsh*

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